REMARKS

Claims 1-9, 11-17 and 19 are pending. No new matter has been added by way of the present amendment. For instance, newly added claim 19 is supported by, for example, the paragraph spanning pages 19 and 20 of the originally filed specification or page 17, lines 7-21 of the substitute specification. Accordingly, no new matter has been added.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. §103(a)

The Examiner has rejected claims 1, 3-9, 11, and 13-17 under 35 U.S.C. §103(a) as being obvious over Bradfield, U.S. Patent No. 5,650,283 (herein Bradfield) in view of Waldman et al., *Analytical Biochemistry,* 258:216-222(1998) (herein Waldman).

The Examiner has also rejected claims claims 2 and 12 under 35 U.S.C. §103(a) as being obvious over Bradfield in view of Waldman and Kushner, U.S. Patent No. 6,117,638 (herein Kushner).

Applicants respectfully traverse each of the above rejections.

The Present Invention and its Advantages

The present invention, for instance as defined in claim 1, relates to an animal cell expressing a gene coding a ligand-responsive transcription control factor and stably transformed with a DNA comprising genes (a) and (b) in a molecule, wherein gene (a) is a reporter gene connected downstream from a transcription control region, in which said transcription control region substantially consists of a recognition sequence of said ligand-responsive transcription

control factor and a minimum promoter which can function in said cell, and gene (b) is a selective marker gene which can function in said cell. The animal cell is further characterized by the fact that gene (c), which is a reporter gene connected downstream from a promoter which transcription activity is unchanged by having said ligand-responsive transcription control factor contacted with a ligand of said ligand-responsive transcription control factor, said reporter gene (c) coding a protein which can be differentiated from the protein coded by said gene (a), is not present in said cell.

The Examiner's attention is drawn to the fact that the reporter gene (a) is connected downstream from a transcription control region which substantially consists of a recognition sequence of the ligand-responsive transcription control factor and a minimum promoter. In the presently claimed cell, as a result of the specific limitations, the constitutive background transcription activity is lowered. Since such background activity hinders the measurement of transcription activity, the lowering of such background activity allows for higher sensitivity in the detection of ligand-responsive transcription activity. Also, the Examiner's attention is drawn to newly added claim 19, wherein the minimum promoter is defined as a minimum promoter of a metallothionein I gene or an ovalbumin gene. Such a minimum promoter is a DNA having a region which determines the transcription initiation site and relates to maintaining the transcription level.

<u>Distinctions between the Present Invention and the Cited Art</u>

Applicants respectfully submit that the references cited by the Examiner, whether taken alone or in combination, fail to suggest or disclose the presently claimed subject matter. For

instance, Bradfield, Waldman and Kushner each fail to suggest or disclose an animal cell stably transformed with a DNA comprising in a molecule, a reporter gene (a) connected downstream from a transcription control region which substantially consists of a recognition sequence of the ligand-responsive transcription control factor and a minimum promoter, and a selective marker gene (b). As such, these references fail to recognize the fact that the present animal cell exhibits higher sensitivity in the detection of ligand-responsive transcription activity.

The Federal Circuit has explained that "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable expectation of success. *Rockwell Int'l Corp. v. United States*, 47 USPQ2d 1027, 1033 (Fed. Cir. 1998). Thus, the prior art must first suggest or provide motivation to one of ordinary skill in the art that the subject matter claimed should be pursued. Then, there must be a reasonable expectation of success. However, in the present instance the cited art fails as a whole to suggest or disclose a DNA comprising in a molecule, a reporter gene (a) connected downstream from a transcription control region which substantially consists of a recognition sequence of the ligand-responsive transcription control factor and a minimum promoter, and a selective marker gene (b). Based upon this deficiency alone, Applicants submit that the Examiner has failed to present a valid *prima facie* case of obviousness.

However, Applicants further draw the Examiner's attention to newly added claim 19. Claim 19 defines the minimal promoter as a minimum promoter of metallothionein I gene or ovalbumin gene. This limitation concerning a specific minimum promoter is completely absent from the cited art and represents an additional distinction.

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As such, there exist limitations in the present claims, which are completely lacking in each of the cited references. Accordingly, there exists no *prima facie* case of obviousness.

In summary, Applicants respectfully submit that there exists no *prima facie* case of obviousness. Accordingly, the Examiner is requested to withdraw all rejections and allow the currently pending claims.

If there are any minor matters precluding allowance of the application which may be resolved by a telephone discussion, the Examiner is respectfully requested to contact Craig A. McRobbie (Reg. No. 42,874) at (703) 205-8000.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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